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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/758,813
Filing Date: January 16, 2004
Appellant(s): BLAKLEY, DANIEL ROBERT

Walter W. Karnstein
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed July 10, 2007 appealing from the Office action mailed February 27, 2007.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

6,169,919	Nearing et al.	01-2001
3,868,567	Ekstrom	02-1975

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-15 and 27-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Nearing et al. (U.S. Pat. 6,169,919 hereinafter "Nearing").

In regards to claims 1, 10, 27 and 30, Nearing discloses referencing an electrocardial waveform, identifying a trigger, waiting for a period of isoelectric activity, sampling the wave, and dynamically referencing the voltage over a period of the selected beat that can utilize a computerized system (e.g. Col. 1, ll. 66-67 & Col. 2, ll. 1-20; Col. 13, ll. 61-67).

In regards to claims 2-4, 11-12, 28-29 and 31, Nearing discloses that the isoelectric/ zero value is the TP segment and that the segment is determined from the r-wave (e.g. Col. 6. ll. 42-45), followed by negative S peak and the T wave (e.g. Fig. 1).

Examiner notes that when the trigger is the R peak and the sample is "TP" interval, the electrocardial waveform inherently contains a negative S peak and a T-wave included between the trigger and the sample.

In regards to claims 5 and 6, Nearing discloses that the TP interval is at least 0.2 seconds long (e.g. Col. 6, ll. 50-52) and the recording period can be determined either automatically or manually (e.g. Col. 6, ll. 34-60).

In regards to claim 7, Nearing discloses that it uses the isoelectric TP value as a baseline value instead of using a reference value from a reference electrode (e.g. Col. 12, ll. 8-16).

In regards to claims 8 and 32, Nearing discloses that the isoelectric value applied to the waveform is sampled from the TP interval, which is an isoelectric interval in the electrocardial waveform (e.g. Col. 1, ll. 66-67 & Col. 2, ll. 1-2).

In regards to claim 9, Nearing further discloses that it detects frequency modulations in the waveform (e.g. Col. 13, ll. 36-39).

In regards to claim 13, Nearing discloses that the isoelectric period can be the PQ segment which is followed by the QRS complex (e.g. Col. 4, ll. 3-4).

In regards to claim 14, Nearing discloses that the reference value is determined from the rate of change of the isoelectric value of TP (e.g. Col. 2, ll. 1-20).

In regards to claim 15, Nearing discloses a processor configured to run the system as disclosed above (e.g. Fig. 9, "904").

A method for applying a reference value to an electrocardial waveform including a series of heart beats, the method comprising:	Determining an isoelectric value at each of a first isoelectric point in a first beat, a second isoelectric point in a second beat and a third isoelectric point in a third beat of the ECG data, fitting a spline curve to the first three isoelectric values, subtracting the values of the spline curve from the corresponding values of the ECG data. Then repeating the process until a desired plurality of beats in the ECG data have been processed (*See* Col. 1, ll. 66-67 & Col. 2, ll. 1-20).
identifying a triggering event within the electrocardial waveform;	The location of the TP segment is based on the apex of the R-wave. (Col. 6, ll. 43-45)
waiting a period of time after the triggering event for an interval of relative inactivity in the waveform;	Waiting 0.5s to sample the TP segment after the apex of the R-wave. (Col. 6, ll. 42-45 & 50-52)
sampling the electrocardial waveform during the interval of relative inactivity to provide a sample voltage value corresponding to a selected beat; and	The isoelectric value is represented by a point on the TP segment (Col. 4, ll. 4-6). Similarly, the R-R interval can be used as a triggering event and therefore comprises

	two events (Col. 6, ll. 45-47).
dynamically referencing the electrocardial waveform to the sample voltage value over a period of the selected beat.	Determining an isoelectric value at each of a first isoelectric point in a first beat, a second isoelectric point in a second beat and a third isoelectric point in a third beat of the ECG data, fitting a spline curve to the first three isoelectric values, subtracting the values of the spline curve from the corresponding values of the ECG data. Then repeating the process until a desired plurality of beats in the ECG data have been processed (*See* Col. 1, ll. 66-67 & Col. 2, ll. 1-20). Further, Nearing states that the promising results indicated that the present invention is ideal for use in real-time calculations (Col. 13, ll. 61-62).

Claims 16-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nearing in view of Ekstrom (U.S. Pat. 3,868,567).

Regarding claims 16-26, Nearing discloses the claimed subject matter as disclosed in detail above and a digital system (e.g. Col. 10, ll. 25-30), but Nearing fails to show a analog circuit capable of creating a reference voltage. However Ekstrom discloses a method and apparatus for analysis of an isoelectric value in an electrocardial waveform, which includes a clock (48), analog sampler (52), amplifier/generator (44) and a peak detector/trigger (42). The system of Ekstrom samples an electrocardial waveform, finds an isoelectric sample within the waveform for a reference voltage, subtracts the reference voltage from the waveform using an amplifier, and outputs the final waveform (e.g. Col. 3, ll. 44-67 & Col. 4, ll. 1-40).

Regarding claims 16-26, Nearing discloses the claimed invention except for the analog circuitry. Ekstrom teaches that it is known to use analog circuitry to detect and

measure and isoelectric area of a electrocardial signal. Both Nearing and Ekstrom teach systems to analyze and filter electrocardial waveforms and thus teach of analogous art. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the digital system for referencing electrocardial waveforms as taught by Nearing, with analog system as taught by Ekstrom, since such a modification would provide the electrocardial waveform with a analog system that filters and analyzes a electrocardial waveform in real time in a simplified fashion to reduce costs.

(10) Response to Argument

Rejections under 35 U.S.C § 102

In regards to claim 1, the Appellant argues at page 5 of the Appeal Brief that Nearing does not disclose dynamic referencing of a voltage value over a period of a beat. The Appellant further argues that Nearing discloses subtracting values of the spline curve from the corresponding values of the ECG data. The Examiner respectfully disagrees. Nearing discloses sampling an electrocardial waveform during a period of relative inactivity ("isoelectric") that corresponds to a specific beat and creating a spline curve. Nearing then references the electrocardial waveform to the sampled value over a period of a selected beat (Col. 1, ll. 66-67 & Col. 2, ll. 1-20). Nearing further discloses that this is done in real-time (Col. 13, ll. 61-67). The Appellant drafted the claim in a comprising format, an open ended claim, and thus the claim does not preclude the use of other beats. Although Nearing may sample over several beats, Nearing still meets the open-ended claim format of, "comprising ... sampling the electrocardial waveform

during the interval of relative inactivity to provide a sample voltage value corresponding to a selected beat; and dynamically referencing the electrocardial waveform to the sampled voltage value over a period of the selected beat", since Nearing uses the multiple samples that include the sample from the selected beat to reference the selected beat. The sampled isoelectric value for each beat is used to reference the electrocardial waveform over the selected beat wherein Nearing uses the sampled voltage from the isoelectric value from the beat to reference the electrocardial waveform during that same beat.

In regards to claim 10, the Appellant argues at page 6 of the Appeal Brief that Nearing does not disclose manipulation or referencing of any voltage signals. The Appellant further argues that Nearing does not manipulate any analog signals. The Examiner respectfully disagrees. The Appellant's claim 10 does not state that the referencing element or any element of the claim must be an analog component. While Nearing converts the analog signal to a digital signal, the values of the digital signal are still representative of a voltage signal. As discussed above, Nearing discloses that the sampled value (a voltage) is referenced over a period of the selected beat.

In regards to claim 27, the Appellant argues at page 6 of the Appeal Brief that Nearing does not disclose the use of first and second features as triggering events. The Examiner respectfully disagrees. The Appellant's claim 27 does not require multiple triggers, the claim states, "... wherein the triggering event includes a first and second feature of the electrocardial waveform". Note, the claim does not state that the first and second features are used to trigger anything, just that the triggering event has a first

and second feature. In addition, Nearing discloses the R-R interval is used as a triggering event and therefore comprises two events (Col. 6, ll. 45-47). Further when the trigger is the R peak and the sample is "TP" interval, the trigger would consist of the section of the electrocardial waveform from the R peak to the "TP" interval, which inherently contains a negative S peak and a T-wave. Thus, the trigger contains multiple features of the electrocardial waveform.

Rejections under 35 U.S.C § 103

In regards to claims 16 and 22, the Appellant argues at page 9 of the Appeal Brief that neither Nearing nor Ekstrom disclose analog components that apply a voltage to an incoming signal. The applicant further argues that Ekstrom discloses only binary signal diagrams. It is noted that Ekstrom was cited for its prior art section as noted in the figures and columns cited in the rejection. The prior art section discusses analog circuitry that accomplishes the same tasks as those of Nearing. The prior art section of Ekstrom disclosed in column 3, lines 44-67 and column 4, lines 1-40, describes analog circuitry to measure an isoelectric area to get a reference voltage, subtract the voltage from the waveform and then output the final waveform. The arguments of the Appellant relate to the improvements of Ekstrom and not to the prior art section of Ekstrom cited in the rejection. Thus the Appellant's arguments regarding claims 16 and 22 are moot.

Nearing discloses the claimed invention except for the analog circuitry. Ekstrom teaches that it is known to use analog circuitry to detect and measure and isoelectric area of an electrocardial signal. Both Nearing and Ekstrom teach systems to analyze and filter electrocardial waveforms and thus teach of analogous art. It would have been

obvious to one having ordinary skill in the art at the time the invention was made to modify the digital system for referencing electrocardial waveforms as taught by Nearing, with analog system as taught by Ekstrom, since such a modification would provide the electrocardial waveform system with a analog system that filters and analyzes a electrocardial waveform in real time in a simplified fashion to reduce costs.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Rex Holmes

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